

Serial No.: 10/666,451
Examiner: David Isabella
Art Unit: 3738

REMARKS

Claims 1-39 are pending in the application. Claims 2, 19-26 and 30 have been canceled.

The remaining claims have been rejected under 35 U.S.C. § 103(a) as obvious over Shea in view of Kurz, Muller or Gersdorff. The applicant respectfully traverses the Examiner's rejections for the following reasons.

Claim 1 has been amended to include the limitation of claim 2, that the spring-loaded handle is constructed of titanium. The Examiner states that Kurz teaches making the bight for capturing the incus from pure titanium and that it would have been obvious to replace the stainless steel bight of Shea with the spring-like titanium bight of Kurz. This argument is problematic in that *Kurz does not teach a titanium bight*. Kurz teaches a titanium hook 13 for anchoring to the hammer and a titanium collar 23, 33 on the anvil leg. Neither of these elements is a bight or handle on a bucket for capturing the incus, and Kurz fails to provide any teaching or suggestion for the claimed titanium handle. Furthermore, with respect to claim 3, Kurz fails to teach the use of commercial pure grade 4 titanium. Similar arguments as above are applicable to claims 9, 10 and 13.

With respect to claims 8, 14, 29 and 31-39, such claims require a stapedial prosthesis having a bucket with a plurality of slots defining wall segments, a portion of the bucket being adjustable in diameter by manipulation of the wall segments and

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retaining the adjusted diameter after a force causing the adjusted diameter is removed.
(limitation specifically from claim 14, but similar language in other claims)

In distinction, Muller teaches a driver for coupling an implantable hearing system in which a ball receiver 79 of a spring-loaded ball and socket arrangement is provided with slots. The slotted wall of the receiver 79 is not adapted to retain any change in diameter. As soon as the ball head 80 of the coupling rod 19 is removed, the ball receiver 79 "can [and does] spring reversibly" (col. 9, lines 5-6). Thus, any change in diameter is temporary. Furthermore, the slotted receiver of Muller is only effective for a ball and socket engagement. However, an incus which the bucket is sized to receive is not ball shaped. In view of the foregoing, Shea in view of Muller fails to teach or suggest a bucket with slotted wall system which (i) maintains its adjusted diameter after the force causing the adjusted diameter is removed, (ii) captures a structure which is not ball-shaped, and (iii) is used with an anatomical structure, and particularly the incus (claims 29 and 31).

Furthermore, the order of bending and moving (claims 32, 33) is not taught or suggested. In addition, the art fails to teach or suggest "biasing the incus relative to the bucket with the spring-loaded bail handle" (claim 37). Also, for reasons advanced above, there is no teaching or suggestion to provide a titanium bail handle (claim 38).

Claim 27 requires a stapedial prosthesis having a body with a bucket with a radial center and a handle element having ends which are detached from each other but located

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within the body, but do not extend to or past said radial center of said body. In Shea, the ends of the handle are coupled together and meet at the radial center 38.

Claim 28 requires a stapedial prosthesis having a handle element having first and second ends (i) each being uncoupled from the other, (ii) each being located within said body, and (iii) each not passing the other within said bucket. This is not suggested by the prior art of record.

New claims 41-47 claim aspects of the shaft of the prosthesis. The Examiner has argued with respect to canceled claims that Prescott discloses claimed elements of the shaft of the stapedial prosthesis. The applicant traverse for the following reasons.

First, Prescott teaches a universal middle ear prosthesis in which either the first portion 12 is used for replacement of the malleus and incus (col. 2, line 51-53) or the first and second portions 12, 14 are used in combination for replacement of all three ossicles (malleus, incus and stapes) (col. 2, lines 56-57). Second portion 14 is not intended, nor does it include sufficient structure, to be used alone to replace the stapes. Thus, Prescott does not teach a stapedial prosthesis as claimed.

Second, the claimed dimensions are provided for different reasons than that provided for in Prescott. In Prescott, the reduced diameter portion is stated to allow "easier fitting of prosthesis 10 within the narrow bony opening of the middle ear near the stapes." (col. 3, lines 6-8). The claimed stepped diameter "provides a visual cue for the

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surgeon as the surgeon places the prosthesis into the opening made in the oval window. The smaller diameter central portion of the shaft also helps to reduce the mass of the device thus aiding in the sound energy transmission from the tympanic membrane to the inner ear."

Third, the claims all depend on claims which are allowable for other reasons advanced above.

New claims 48 and 49 have been added to more completely claim the invention. The claim requires "a titanium spring-loaded handle coupled to said bucket, wherein a constant force is required to rotate said handle relative to said bucket completely through a permitted degree of rotation" and that the degree of rotation is approximately 180°. See Figs 11 and 12. In distinction, the bail handle of Shea is highly uncontrollable, requiring different amounts of force for movement as it is rotated over the cam. As it is forced passed the apex of the cam, the handle snaps into a locked position, which can be an unpleasant surprise for the surgeon. The prior art of record does not teach or suggest the claimed invention.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain

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outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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